

## Calendar No. 647

117TH CONGRESS  
2D SESSION

# S. 4293

To prevent unfair and deceptive acts or practices and the dissemination of false information related to pharmacy benefit management services for prescription drugs, and for other purposes.

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### IN THE SENATE OF THE UNITED STATES

MAY 24, 2022

Ms. CANTWELL (for herself, Mr. GRASSLEY, Mr. BOOZMAN, Mr. BRAUN, Mr. MORAN, Mr. TILLIS, Mr. TESTER, Mrs. HYDE-SMITH, and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

DECEMBER 14, 2022

Reported by Ms. CANTWELL, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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## A BILL

To prevent unfair and deceptive acts or practices and the dissemination of false information related to pharmacy benefit management services for prescription drugs, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the "Pharmacy Benefit  
3 Manager Transparency Act of 2022".

4 **SEC. 2. PROHIBITION ON UNFAIR OR DECEPTIVE PRE-  
5SCRIPTION DRUG PRICING PRACTICES.**

6 (a) CONDUCT PROHIBITED.—Except as provided in  
7 subsection (b), it shall be unlawful for any pharmacy ben-  
8 efit manager (or affiliate, subsidiary, or agent of a phar-  
9 macy benefit manager), directly or indirectly, to engage  
10 in any of the following activities related to pharmacy ben-  
11 efit management services:

12 (1) Charge a health plan or payer a different  
13 amount for a prescription drug's ingredient cost or  
14 dispensing fee than the amount the pharmacy ben-  
15 efit manager reimburses a pharmacy for the pre-  
16 scription drug's ingredient cost or dispensing fee  
17 where the pharmacy benefit manager retains the  
18 amount of any such difference.

19 (2) Arbitrarily, unfairly, or deceptively, by con-  
20 tract or any other means, reduce, rescind, or other-  
21 wise claw back any reimbursement payment, in  
22 whole or in part, to a pharmacist or pharmacy for  
23 a prescription drug's ingredient cost or dispensing  
24 fee.

25 (3) Arbitrarily, unfairly, or deceptively, by con-  
26 tract or any other means, increase fees or lower re-

1       imbursement to a pharmacy in order to offset reim-  
2       bursement changes instructed by the Federal Gov-  
3       ernment under any health plan funded by the Fed-  
4       eral Government.

5       (b) EXCEPTIONS.—A pharmacy benefit manager  
6       shall not be in violation of subsection (a) if the pharmacy  
7       benefit manager meets the following conditions:

8              (1) The pharmacy benefit manager, affiliate,  
9       subsidiary, or agent passes along or returns 100 per-  
10       cent of any price concession to a health plan or  
11       payer, including any rebate, discount, or other price  
12       concession.

13              (2) The pharmacy benefit manager, affiliate,  
14       subsidiary, or agent provides full and complete dis-  
15       closure of—

16                  (A) the cost, price, and reimbursement of  
17       the prescription drug to each health plan,  
18       payer, and pharmacy with which the pharmacy  
19       benefit manager, affiliate, subsidiary, or agent  
20       has a contract or agreement to provide phar-  
21       macy benefit management services;

22                  (B) each fee, markup, and discount  
23       charged or imposed by the pharmacy benefit  
24       manager, affiliate, subsidiary, or agent to each  
25       health plan, payer, and pharmacy with which

1           the pharmacy benefit manager, affiliate, subsidiary, or agent has a contract or agreement  
2           for pharmacy benefit management services; or  
3  
4           (C) the aggregate amount of all remuneration the pharmacy benefit manager receives  
5           from a prescription drug manufacturer for a  
6           prescription drug, including any rebate, dis-  
7           count, administration fee, and any other pay-  
8           ment or credit obtained or retained by the phar-  
9           macy benefit manager, or affiliate, subsidiary,  
10           or agent of the pharmacy benefit manager, pur-  
11           suant to a contract or agreement for pharmacy  
12           benefit management services to a health plan,  
13           payer, or any Federal agency (upon the request  
14           of the agency).  
15

16 **SEC. 3. PROHIBITION ON FALSE INFORMATION.**

17           It shall be unlawful for any person to report informa-  
18           tion related to pharmacy benefit management services to  
19           a Federal department or agency if—

20           (1) the person knew, or reasonably should have  
21           known, the information to be false or misleading;

22           (2) the information was required by law to be  
23           reported; and

24           (3) the false or misleading information reported  
25           by the person would affect analysis or information

1       compiled by the Federal department or agency for  
2       statistical or analytical purposes with respect to the  
3       market for pharmacy benefit management services.

4       **SEC. 4. TRANSPARENCY.**

5       (a) **REPORTING BY PHARMACY BENEFIT MAN-**  
6 **AGERS.**—Not later than 1 year after the date of enactment  
7 of this Act, and annually thereafter, each pharmacy ben-  
8 efit manager (or affiliate, subsidiary, or agent of a phar-  
9 macy benefit manager) shall report to the Commission the  
10 following information:

11           (1) The aggregate amount of the difference be-  
12       tween the amount the pharmacy benefit manager  
13       was paid by each health plan and the amount that  
14       the pharmacy benefit manager paid each pharmacy  
15       on behalf of the health plan for prescription drugs.

16           (2) The aggregate amount of any—

17              (A) generic effective rate fee charged to  
18       each pharmacy;

19              (B) direct and indirect remuneration fee  
20       charged or other price concession to each phar-  
21       macy; and

22              (C) payment rescinded or otherwise clawed  
23       back from a reimbursement made to each phar-  
24       macy.

1                   (3) If, during the reporting year, the pharmacy  
2 benefit manager moved or reassigned a prescription  
3 drug to a formulary tier that has a higher cost,  
4 higher copayment, higher coinsurance, or higher de-  
5 ductible to a consumer, or a lower reimbursement to  
6 a pharmacy; an explanation of the reason why the  
7 drug was moved or reassigned from 1 tier to an-  
8 other; including whether the move or reassignment  
9 was determined or requested by a prescription drug  
10 manufacturer or other entity.

11                  (4) With respect to any pharmacy benefit man-  
12 ger that owns, controls, or is affiliated with a phar-  
13 macy, a report regarding any difference in reim-  
14 bursement rates or practices, direct and indirect re-  
15 muneration fees or other price concessions, and  
16 clawbacks between a pharmacy that is owned, con-  
17 trolled, or affiliated with the pharmacy benefit man-  
18 ager and any other pharmacy.

19                  (b) REPORT TO CONGRESS.—

20                  (1) IN GENERAL.—Not later than 1 year after  
21 the date of enactment of this Act, and annually  
22 thereafter, the Commission shall submit to the Com-  
23 mittee on Commerce, Science, and Transportation of  
24 the Senate and the Committee on Energy and Com-

1       merce of the House of Representatives a report that  
2       addresses, at a minimum—

3                 (A) the number actions brought by the  
4       Commission during the reporting year to en-  
5       force this Act and the outcome of each such en-  
6       forcement action;

7                 (B) the number of open investigations or  
8       inquiries into potential violations of this Act as  
9       of the time the report is submitted;

10                (C) the number and nature of complaints  
11       received by the Commission relating to an alle-  
12       gation of a violation of this Act during the re-  
13       porting year;

14                (D) an anonymized summary of the re-  
15       ports filed with the Commission pursuant to  
16       subsection (a) for the reporting year; and

17                (E) policy or legislative recommendations  
18       to strengthen any enforcement action relating  
19       to a violation of this Act, including rec-  
20       ommendations to include additional prohibited  
21       conduct in section 2(a).

22                (2) FORMULARY DESIGN OR PLACEMENT PRAC-  
23       TICES.—Not later than 1 year after the date of en-  
24       actment of this Act, the Commission shall submit to  
25       the Committee on Commerce, Science, and Trans-

1 portation of the Senate and the Committee on Energy and Commerce of the House of Representatives  
2 a report that addresses the policies, practices, and  
3 role of pharmacy benefit managers (including their  
4 affiliates, subsidiaries, and agents) regarding formulary design or placement, including whether—  
5

6                   (A) pharmacy benefit managers (including  
7                   their affiliates, subsidiaries, and agents) use  
8                   formulary design or placement to increase their  
9                   gross revenue without an accompanying in-  
10                  crease in patient access or decrease in patient  
11                  cost; or  
12

13                   (B) such policies or practices of pharmacy  
14                  benefit managers regarding formulary design or  
15                  placement violate section 5(a) of the Federal  
16                  Trade Commission Act (45 U.S.C. 45(a)).

17                   (3) CONSTRUCTION.—Nothing in this section  
18                  shall be construed as authorizing the Commission to  
19                  disclose any information that is a trade secret or  
20                  confidential information described in section  
21                  552(b)(4) of title 5, United States Code.

22 **SEC. 5. WHISTLEBLOWER PROTECTIONS.**

23                   (a) IN GENERAL.—A pharmacy benefit manager,  
24                  health plan, pharmaceutical manufacturer, pharmacy, or  
25                  any affiliate, subsidiary, or agent thereof shall not, directly

1 or indirectly, discharge, demote, suspend, diminish, or  
2 withdraw benefits from, threaten, harass, or in any other  
3 manner discriminate against or adversely impact a covered  
4 individual because—

5           (1) the covered individual, or anyone perceived  
6 as assisting the covered individual, takes (or is sus-  
7 peeted to have taken or will take) a lawful action in  
8 providing to Congress, an agency of the Federal  
9 Government, the attorney general of a State, a State  
10 regulator with authority over the distribution or in-  
11 surance coverage of prescription drugs, or a law en-  
12 forcement agency relating to any act or omission  
13 that the covered individual reasonably believes to be  
14 a violation of this Act;

15           (2) the covered individual provides information  
16 that the covered individual reasonably believes evi-  
17 dences such a violation to—

18           (A) a person with supervisory authority  
19 over the covered individual at the pharmacy  
20 benefit manager, health plan, pharmaceutical  
21 manufacturer, pharmacy, or any affiliate, sub-  
22 sidiary, or agent thereof; or

23           (B) another individual working for the  
24 pharmacy benefit manager, health plan, phar-  
25 maceutical manufacturer, pharmacy, or any af-

1           affiliate, subsidiary, or agent thereof who the cov-  
2         ered individual reasonably believes has the au-  
3         thority to investigate, discover, or terminate the  
4         violation or to take any other action to address  
5         the violation;

6           (3) the covered individual testifies (or it is sus-  
7         pected that the covered individual will testify) in an  
8         investigation or judicial or administrative proceeding  
9         concerning such a violation;

10          (4) the covered individual assists or participates  
11         (or it is expected that the covered individual will as-  
12         sist or participate) in such an investigation or judi-  
13         cial or administrative proceeding; or

14          (5) the covered individual takes any other ac-  
15         tion to assist in carrying out the purposes of this  
16         Act.

17          (b) ENFORCEMENT.—An individual who alleges any  
18         adverse action in violation of subsection (a) may bring an  
19         action for a jury trial in the appropriate district court of  
20         the United States for the following relief:

21          (1) Temporary relief while the case is pending.

22          (2) Reinstatement with the same seniority sta-  
23         tus that the individual would have had, but for the  
24         discharge or discrimination.

1                   (3) Twice the amount of back pay otherwise  
2 owed to the individual, with interest.

3                   (4) Consequential and compensatory damages,  
4 and compensation for litigation costs, expert witness  
5 fees, and reasonable attorneys' fees.

6                   (e) WAIVER OF RIGHTS AND REMEDIES.—The rights  
7 and remedies provided for in this section shall not be  
8 waived by any policy form or condition of employment, in-  
9 cluding by a predispute arbitration agreement.

10                  (d) PREDISPUTE ARBITRATION AGREEMENTS.—No  
11 predispute arbitration agreement shall be valid or enforce-  
12 able if the agreement requires arbitration of a dispute  
13 arising under this section.

14 **SEC. 6. ENFORCEMENT.**

15                  (a) ENFORCEMENT BY THE COMMISSION.—

16                  (1) UNFAIR AND DECEPTIVE ACTS OR PRAC-  
17 TICES.—A violation of this Act shall be treated as  
18 a violation of a rule defining an unfair or deceptive  
19 act or practice under section 18(a)(1)(B) of the Fed-  
20 eral Trade Commission Act (15 U.S.C.  
21 57a(a)(1)(B)).

22                  (2) POWERS OF THE COMMISSION.—

23                  (A) IN GENERAL.—Except as provided in  
24 subparagraph (C), the Commission shall enforce  
25 this Act in the same manner, by the same

1 means, and with the same jurisdiction, powers,  
2 and duties as though all applicable terms and  
3 provisions of the Federal Trade Commission  
4 Act (15 U.S.C. 41 et seq.) were incorporated  
5 into and made a part of this Act.

6 (B) PRIVILEGES AND IMMUNITIES.—Sub-  
7 ject to paragraph (3), any person who violates  
8 this Act shall be subject to the penalties and  
9 entitled to the privileges and immunities pro-  
10 vided in the Federal Trade Commission Act (15  
11 U.S.C. 41 et seq.).

12 (C) NONPROFIT ORGANIZATIONS AND IN-  
13 SURANCE.—Notwithstanding section 4 or 6 of  
14 the Federal Trade Commission Act (15 U.S.C.  
15 44, 46), section 2 of McCarran-Ferguson Act  
16 (15 U.S.C. 1012), or any other jurisdictional  
17 limitation of the Commission, the Commission  
18 shall also enforce this Act, in the same manner  
19 provided in subparagraphs (A) and (B) of this  
20 paragraph, with respect to—

21 (i) organizations not organized to  
22 carry on business for their own profit or  
23 that of their members; and

24 (ii) the business of insurance, and  
25 persons engaged in such business.

1                             (D) AUTHORITY PRESERVED.—Nothing in  
2                             this section shall be construed to limit the au-  
3                             thority of the Commission under any other pro-  
4                             vision of law.

5                             (3) PENALTIES.—

6                             (A) ADDITIONAL CIVIL PENALTY.—In ad-  
7                             dition to any penalty applicable under the Fed-  
8                             eral Trade Commission Act (15 U.S.C. 41 et  
9                             seq.), any person that violates this Act shall be  
10                            liable for a civil penalty of not more than  
11                            \$1,000,000.

12                            (B) METHOD.—The penalties provided by  
13                             subparagraph (A) shall be obtained in the same  
14                             manner as civil penalties imposed under section  
15                             18(a)(1)(B) of the Federal Trade Commission  
16                             Act (15 U.S.C. 57a(a)(1)(B)).

17                            (C) MULTIPLE OFFENSES; MITIGATING  
18                             FACTORS.—In assessing a penalty under sub-  
19                             paragraph (A)—

20                                 (i) each day of a continuing violation  
21                             shall be considered a separate violation;  
22                             and

23                                 (ii) the court shall take into consider-  
24                             ation, among other factors—

1                             (I) the seriousness of the violation;

3                             (II) the efforts of the person  
4                             committing the violation to remedy  
5                             the harm caused by the violation in a  
6                             timely manner; and

7                             (III) whether the violation was  
8                             intentional.

9                             (b) ENFORCEMENT BY STATES.—

10                             (I) IN GENERAL.—If the attorney general of a  
11                             State has reason to believe that an interest of the  
12                             residents of the State has been or is being threat-  
13                             ened or adversely affected by a practice that violates  
14                             this Act, the attorney general of the State may bring  
15                             a civil action on behalf of the residents of the State  
16                             in an appropriate district court of the United States  
17                             to obtain appropriate relief.

18                             (2) RIGHTS OF THE COMMISSION.—

19                             (A) NOTICE TO THE COMMISSION.—

20                             (i) IN GENERAL.—Except as provided  
21                             in clause (iii), the attorney general of a  
22                             State, before initiating a civil action under  
23                             paragraph (1), shall provide written notifi-  
24                             cation to the Commission that the attorney  
25                             general intends to bring such civil action.

1                             (ii) CONTENTS.—The notification re-  
2                             quired under clause (i) shall include a copy  
3                             of the complaint to be filed to initiate the  
4                             civil action.

5                             (iii) EXCEPTION.—If it is not feasible  
6                             for the attorney general of a State to pro-  
7                             vide the notification required under clause  
8                             (i) before initiating a civil action under  
9                             paragraph (1), the attorney general shall  
10                          notify the Commission immediately upon  
11                          instituting the civil action.

12                          (B) INTERVENTION BY THE COMMISSION.—The Commission may—

14                          (i) intervene in any civil action  
15                          brought by the attorney general of a State  
16                          under paragraph (1); and

17                          (ii) upon intervening—

18                          (I) be heard on all matters aris-  
19                          ing in the civil action; and

20                          (II) file petitions for appeal of a  
21                          decision in the civil action.

22                          (3) CONSTRUCTION.—Nothing in this sub-  
23                          section may be construed to prevent the attorney  
24                          general of a State from exercising the powers con-  
25                          ferred on the attorney general by the laws of the

1 State to conduct investigations, to administer oaths  
2 or affirmations, or to compel the attendance of wit-  
3 nesses or the production of documentary or other  
4 evidence.

5 (4) VENUE; SERVICE OF PROCESS.—

6 (A) VENUE.—Any action brought under  
7 paragraph (1) may be brought in—

- 8 (i) the district court of the United  
9 States that meets applicable requirements  
10 relating to venue under section 1391 of  
11 title 28, United States Code; or  
12 (ii) another court of competent juris-  
13 diction.

14 (B) SERVICE OF PROCESS.—In an action  
15 brought under paragraph (1), process may be  
16 served in any district in which—

- 17 (i) the defendant is an inhabitant,  
18 may be found, or transacts business; or  
19 (ii) venue is proper under section  
20 1391 of title 28, United States Code.

21 (5) ACTIONS BY OTHER STATE OFFICIALS.—

22 (A) IN GENERAL.—In addition to a civil  
23 action brought by an attorney general under  
24 paragraph (1), any other officer of a State who  
25 is authorized by the State to do so may bring

1           a civil action under paragraph (1), subject to  
2           the same requirements and limitations that  
3           apply under this subsection to civil actions  
4           brought by attorneys general.

5           (B) SAVINGS PROVISION.—Nothing in this  
6           subsection may be construed to prohibit an au-  
7           thorized official of a State from initiating or  
8           continuing any proceeding in a court of the  
9           State for a violation of any civil or criminal law  
10           of the State.

11           (c) AFFIRMATIVE DEFENSE.—In an action brought  
12           under this section to enforce section 2, it shall be an af-  
13           firmative defense, on which the defendant has the burden  
14           of persuasion by a preponderance of the evidence, that the  
15           conduct alleged to be a violation of section 2 was  
16           nonpretextual and reasonably necessary to—

17           (1) prevent a violation of, or comply with, Fed-  
18           eral or State law;  
19           (2) protect patient safety; or  
20           (3) protect patient access.

21 **SEC. 7. EFFECT ON STATE LAWS.**

22           Nothing in this Act shall be construed to preempt,  
23           displace, or supplant any State laws, rules, regulations,  
24           or requirements, or the enforcement thereof.

## 1 SEC. 8. DEFINITIONS.

2 In this Act:

3 (1) COMMISSION.—The term “Commission”  
4 means the Federal Trade Commission.5 (2) COVERED INDIVIDUAL.—The term “covered  
6 individual” means a current or former employee,  
7 contractor, subcontractor, service provider, or agent  
8 of a pharmacy benefit manager, health plan, phar-  
9 maceutical manufacturer, pharmacy, or any affiliate,  
10 subsidiary, or agent thereof.11 (3) HEALTH PLAN.—The term “health plan”  
12 means any group or individual health insurance plan  
13 or coverage, including any health insurance plan or  
14 coverage sponsored or funded by the Federal Gov-  
15 ernment or the government of any State, Territory,  
16 or subdivision thereof.17 (4) PHARMACY BENEFIT MANAGER.—The term  
18 “pharmacy benefit manager” means any entity that  
19 provides pharmacy benefit management services on  
20 behalf of a health plan, a payer, or health insurance  
21 issuer.22 (5) PHARMACY BENEFIT MANAGEMENT SERV-  
23 ICES.—The term “pharmacy benefit management  
24 services” means, pursuant to a written agreement  
25 with a payer or health plan offering group or indi-

1       vidual health insurance coverage, directly or through  
2       an intermediary, the service of—

3                   (A) negotiating terms and conditions, in-  
4       cluding rebates and price concessions, with re-  
5       spect to a prescription drug on behalf of the  
6       health plan, coverage, or payer; or

7                   (B) managing the prescription drug bene-  
8       fits provided by the health plan, coverage, or  
9       payer, which may include formulary manage-  
10      ment the processing and payment of claims for  
11      prescription drugs, the performance of drug uti-  
12      lization review, the processing of drug prior au-  
13      thorization requests, the adjudication of appeals  
14      or grievances related to the prescription drug  
15      benefit, contracting with network pharmacies,  
16      or the provision of related services.

17                  (6) **PRESCRIPTION DRUG.**—The term “prescrip-  
18      tion drug” means—

19                   (A) a drug, as that term is defined in sec-  
20      tion 201(g) of the Federal Food, Drug, and  
21      Cosmetic Act (21 U.S.C. 321(g)), that is—

22                   (i) approved by the Food and Drug  
23      Administration under section 505 of such  
24      Act (21 U.S.C. 355); and

1                             (ii) subject to the requirements of sec-  
2                             tion 503(b)(1) of such Act (21 U.S.C.  
3                             353(b)(1));  
4                             (B) a biological product as that term is de-  
5                             fined in section 351 of the Public Health Serv-  
6                             ice Act (42 U.S.C. 262(i)(1)); or  
7                             (C) a product that is biosimilar to, or  
8                             interchangeable with, a biologic product under  
9                             section 351 of the Public Health Service Act  
10                             (42 U.S.C. 262(i)).

11 **SECTION 1. SHORT TITLE.**

12         *This Act may be cited as the “Pharmacy Benefit Man-  
13 ager Transparency Act of 2022”.*

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20 any of the following activities related to pharmacy benefit  
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23 amount for a prescription drug’s ingredient cost or  
24 dispensing fee than the amount the pharmacy benefit  
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1       *drug's ingredient cost or dispensing fee where the  
2       pharmacy benefit manager retains the amount of any  
3       such difference.*

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5       tract or any other means, reduce, rescind, or other-  
6       wise claw back any reimbursement payment, in whole  
7       or in part, to a pharmacist or pharmacy for a pre-  
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10      tract or any other means, increase fees or lower reim-  
11      bursement to a pharmacy in order to offset reimburse-  
12      ment changes instructed by the Federal Government  
13      under any health plan funded by the Federal Govern-  
14      ment.*

15       *(b) EXCEPTIONS.—A pharmacy benefit manager shall  
16      not be in violation of subsection (a) if the pharmacy benefit  
17      manager meets the following conditions:*

18           *(1) The pharmacy benefit manager, affiliate,  
19       subsidiary, or agent passes along or returns 100 per-  
20       cent of any price concession to a health plan or  
21       payer, including any rebate, discount, or other price  
22       concession.*

23           *(2) The pharmacy benefit manager, affiliate,  
24       subsidiary, or agent provides full and complete disclo-  
25       sure of—*

- 1                   (A) the cost, price, and reimbursement of  
2                   the prescription drug to each health plan, payer,  
3                   and pharmacy with which the pharmacy benefit  
4                   manager, affiliate, subsidiary, or agent has a  
5                   contract or agreement to provide pharmacy ben-  
6                   efit management services;
- 7                   (B) each fee, markup, and discount charged  
8                   or imposed by the pharmacy benefit manager, af-  
9                   filiate, subsidiary, or agent to each health plan,  
10                  payer, and pharmacy with which the pharmacy  
11                  benefit manager, affiliate, subsidiary, or agent  
12                  has a contract or agreement for pharmacy ben-  
13                  efit management services; or
- 14                  (C) the aggregate amount of all remunera-  
15                  tion the pharmacy benefit manager receives from  
16                  a prescription drug manufacturer for a prescrip-  
17                  tion drug, including any rebate, discount, ad-  
18                  ministration fee, and any other payment or  
19                  credit obtained or retained by the pharmacy ben-  
20                  efit manager, or affiliate, subsidiary, or agent of  
21                  the pharmacy benefit manager, pursuant to a  
22                  contract or agreement for pharmacy benefit man-  
23                  agement services to a health plan, payer, or any  
24                  Federal agency (upon the request of the agency).

1     **SEC. 3. PROHIBITION ON FALSE INFORMATION.**

2         *It shall be unlawful for any person to report informa-*  
3         *tion related to pharmacy benefit management services to*  
4         *a Federal department or agency if—*

5             *(1) the person knew, or reasonably should have*  
6             *known, the information to be false or misleading;*

7             *(2) the information was required by law to be re-*  
8             *ported; and*

9             *(3) the false or misleading information reported*  
10          *by the person would affect analysis or information*  
11          *compiled by the Federal department or agency for*  
12          *statistical or analytical purposes with respect to the*  
13          *market for pharmacy benefit management services.*

14     **SEC. 4. TRANSPARENCY.**

15         *(a) REPORTING BY PHARMACY BENEFIT MANAGERS.—*  
16         *Not later than 1 year after the date of enactment of this*  
17         *Act, and annually thereafter, each pharmacy benefit man-*  
18         *ager (or affiliate, subsidiary, or agent of a pharmacy ben-*  
19         *efit manager) shall report to the Commission the following*  
20         *information:*

21             *(1) The aggregate amount of the difference be-*  
22             *tween the amount the pharmacy benefit manager was*  
23             *paid by each health plan and the amount that the*  
24             *pharmacy benefit manager paid each pharmacy on*  
25             *behalf of the health plan for prescription drugs.*

26             *(2) The aggregate amount of any—*

1                   (A) generic effective rate fee charged to each  
2                   pharmacy;

3                   (B) direct and indirect remuneration fee  
4                   charged or other price concession to each phar-  
5                   macy; and

6                   (C) payment rescinded or otherwise clawed  
7                   back from a reimbursement made to each phar-  
8                   macy.

9                   (3) If, during the reporting year, the pharmacy  
10                  benefit manager moved or reassigned a prescription  
11                  drug to a formulary tier that has a higher cost, higher  
12                  copayment, higher coinsurance, or higher deductible  
13                  to a consumer, or a lower reimbursement to a phar-  
14                  macy, an explanation of the reason why the drug was  
15                  moved or reassigned from 1 tier to another, including  
16                  whether the move or reassignment was determined or  
17                  requested by a prescription drug manufacturer or  
18                  other entity.

19                  (4) With respect to any pharmacy benefit man-  
20                  ager that owns, controls, or is affiliated with a phar-  
21                  macy, a report regarding any difference in reimburse-  
22                  ment rates or practices, direct and indirect remunera-  
23                  tion fees or other price concessions, and clawbacks be-  
24                  tween a pharmacy that is owned, controlled, or affili-

1       ated with the pharmacy benefit manager and any  
2       other pharmacy.

3       (b) REPORT TO CONGRESS.—

4           (1) IN GENERAL.—Not later than 1 year after  
5       the date of enactment of this Act, and annually there-  
6       after, the Commission shall submit to the Committee  
7       on Commerce, Science, and Transportation of the  
8       Senate and the Committee on Energy and Commerce  
9       of the House of Representatives a report that address-  
10      es, at a minimum—

11           (A) the number actions brought by the Com-  
12       mission during the reporting year to enforce this  
13       Act and the outcome of each such enforcement ac-  
14       tion;

15           (B) the number of open investigations or in-  
16       quiries into potential violations of this Act as of  
17       the time the report is submitted;

18           (C) the number and nature of complaints  
19       received by the Commission relating to an alle-  
20       gation of a violation of this Act during the re-  
21       porting year;

22           (D) an anonymized summary of the reports  
23       filed with the Commission pursuant to subsection  
24       (a) for the reporting year; and

1                   (E) policy or legislative recommendations to  
2 strengthen any enforcement action relating to a  
3 violation of this Act, including recommendations  
4 to include additional prohibited conduct in  
5 section 2(a).

6                   (2) FORMULARY DESIGN OR PLACEMENT PRAC-  
7 TICES.—Not later than 1 year after the date of enact-  
8 ment of this Act, the Commission shall submit to the  
9 Committee on Commerce, Science, and Transpor-  
10 tation of the Senate and the Committee on Energy  
11 and Commerce of the House of Representatives a re-  
12 port that addresses the policies, practices, and role of  
13 pharmacy benefit managers (including their affiliates,  
14 subsidiaries, and agents) regarding formulary design  
15 or placement, including whether—

16                   (A) pharmacy benefit managers (including  
17 their affiliates, subsidiaries, and agents) use for-  
18 mulary design or placement to increase their  
19 gross revenue without an accompanying increase  
20 in patient access or decrease in patient cost; or  
21                   (B) such policies or practices of pharmacy  
22 benefit managers regarding formulary design or  
23 placement violate section 5(a) of the Federal  
24 Trade Commission Act (15 U.S.C. 45(a)).

1                   (3) CONSTRUCTION.—Nothing in this section  
2 shall be construed as authorizing the Commission to  
3 disclose any information that is a trade secret or con-  
4 fidential information described in section 552(b)(4) of  
5 title 5, United States Code.

6                   (c) GAO STUDY.—Not later than 1 year after the date  
7 of enactment of this Act, the Comptroller General of the  
8 United States shall submit to the Committee on Finance  
9 and the Committee on Health, Education, Labor, and Pen-  
10 sions of the Senate and to the Committee on Ways and  
11 Means and the Committee on Energy and Commerce of the  
12 House of Representatives a report that—

13                   (1) addresses, at minimum—

14                   (A) the role that pharmacy benefit man-  
15 agers play in the pharmaceutical supply chain;

16                   (B) the state of competition among phar-  
17 macy benefit managers, including the market  
18 share for the Nation's 10 largest pharmacy ben-  
19 efit managers;

20                   (C) the use of rebates and fees by pharmacy  
21 benefit managers, including data for each of the  
22 10 largest pharmacy benefit managers that re-  
23 flects, for each drug in the formulary of each  
24 such pharmacy benefit manager—

- 1                             (i) the amount of the rebate passed on  
2                             to patients;  
3                             (ii) the amount of the rebate passed on  
4                             to payors;  
5                             (iii) the amount of the rebate kept by  
6                             the pharmacy benefit manager; and  
7                             (iv) the role of fees charged by the  
8                             pharmacy benefit manager;
- 9                             (D) whether pharmacy benefit managers  
10                            structure their formularies in favor of high-re-  
11                            bate prescription drugs over lower-cost, lower-re-  
12                            bate alternatives;
- 13                             (E) the average prior authorization ap-  
14                            proval time for each of the 10 largest pharmacy  
15                            benefit managers;
- 16                             (F) factors affecting the use of step therapy  
17                            in each of the 10 largest pharmacy benefit man-  
18                            agers; and
- 19                             (G) the extent to which the price that phar-  
20                            macy benefit managers charge payors, such as  
21                            the Medicare program under title XXVIII of the  
22                            Social Security Act (42 U.S.C. 1395 et seq.),  
23                            State Medicaid programs under title XIX of the  
24                            Social Security Act (42 U.S.C. 1396 et seq.), the  
25                            Federal Employees Health Benefits Program

1           *under chapter 89 of title 5, United States Code,*  
2           *or private payors, for a drug is more than such*  
3           *pharmacy benefit managers pay the pharmacy*  
4           *for the drug; and*

5           *(2) provides recommendations for legislative ac-*  
6           *tion to lower the cost of prescription drugs for con-*  
7           *sumers and payors, improve the efficiency of the*  
8           *pharmaceutical supply chain by lowering inter-*  
9           *mediary costs, improve competition in pharmacy ben-*  
10          *efit management, and provide transparency in phar-*  
11          *macy benefit management.*

12 **SEC. 5. WHISTLEBLOWER PROTECTIONS.**

13          (a) *IN GENERAL.—A pharmacy benefit manager,*  
14 *health plan, pharmaceutical manufacturer, pharmacy, or*  
15 *any affiliate, subsidiary, or agent thereof shall not, directly*  
16 *or indirectly, discharge, demote, suspend, diminish, or*  
17 *withdraw benefits from, threaten, harass, or in any other*  
18 *manner discriminate against or adversely impact a covered*  
19 *individual because—*

20           *(1) the covered individual, or anyone perceived*  
21 *as assisting the covered individual, takes (or is sus-*  
22 *pected to have taken or will take) a lawful action in*  
23 *providing to Congress, an agency of the Federal Gov-*  
24 *ernment, the attorney general of a State, a State reg-*  
25 *ulator with authority over the distribution or insur-*

1       *ance coverage of prescription drugs, or a law enforce-*  
2       *ment agency relating to any act or omission that the*  
3       *covered individual reasonably believes to be a viola-*  
4       *tion of this Act;*

5           *(2) the covered individual provides information*  
6       *that the covered individual reasonably believes evi-*  
7       *dences such a violation to—*

8              *(A) a person with supervisory authority*  
9       *over the covered individual at the pharmacy ben-*  
10       *efit manager, health plan, pharmaceutical man-*  
11       *ufacturer, pharmacy, or any affiliate, sub-*  
12       *sidiary, or agent thereof; or*

13              *(B) another individual working for the*  
14       *pharmacy benefit manager, health plan, phar-*  
15       *maceutical manufacturer, pharmacy, or any af-*  
16       *filiate, subsidiary, or agent thereof who the cov-*  
17       *ered individual reasonably believes has the au-*  
18       *thority to investigate, discover, or terminate the*  
19       *violation or to take any other action to address*  
20       *the violation;*

21              *(3) the covered individual testifies (or it is sus-*  
22       *pected that the covered individual will testify) in an*  
23       *investigation or judicial or administrative proceeding*  
24       *concerning such a violation;*

1                   (4) the covered individual assists or participates  
2                   (or it is expected that the covered individual will as-  
3                   sist or participate) in such an investigation or judi-  
4                   cial or administrative proceeding; or

5                   (5) the covered individual takes any other action  
6                   to assist in carrying out the purposes of this Act.

7                   (b) *ENFORCEMENT*.—An individual who alleges any  
8                   adverse action in violation of subsection (a) may bring an  
9                   action for a jury trial in the appropriate district court of  
10                  the United States for the following relief:

11                  (1) Temporary relief while the case is pending.

12                  (2) Reinstatement with the same seniority status  
13                  that the individual would have had, but for the dis-  
14                  charge or discrimination.

15                  (3) Twice the amount of back pay otherwise  
16                  owed to the individual, with interest.

17                  (4) Consequential and compensatory damages,  
18                  and compensation for litigation costs, expert witness  
19                  fees, and reasonable attorneys' fees.

20                  (c) *WAIVER OF RIGHTS AND REMEDIES*.—The rights  
21                  and remedies provided for in this section shall not be  
22                  waived by any policy form or condition of employment, in-  
23                  cluding by a predispute arbitration agreement.

24                  (d) *PREDISPUTE ARBITRATION AGREEMENTS*.—No  
25                  predispute arbitration agreement shall be valid or enforce-

1   able if the agreement requires arbitration of a dispute arising  
2   under this section.

3   **SEC. 6. ENFORCEMENT.**

4       (a) **ENFORCEMENT BY THE COMMISSION.—**

5           (1) **UNFAIR AND DECEPTIVE ACTS OR PRACTICES.**—A violation of this Act shall be treated as a  
6           violation of a rule defining an unfair or deceptive act  
7           or practice under section 18(a)(1)(B) of the Federal  
8           Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

9  
10          (2) **POWERS OF THE COMMISSION.—**

11           (A) **IN GENERAL.**—Except as provided in  
12           subparagraph (C), the Commission shall enforce  
13           this Act in the same manner, by the same means,  
14           and with the same jurisdiction, powers, and duties  
15           as though all applicable terms and provisions  
16           of the Federal Trade Commission Act (15  
17           U.S.C. 41 et seq.) were incorporated into and  
18           made a part of this Act.

19           (B) **PRIVILEGES AND IMMUNITIES.**—Subject  
20           to paragraph (3), any person who violates this  
21           Act shall be subject to the penalties and entitled  
22           to the privileges and immunities provided in the  
23           Federal Trade Commission Act (15 U.S.C. 41 et.  
24           seq.).

1                             (C) *NONPROFIT ORGANIZATIONS AND INSUR-*  
2                             *ANCE.—Notwithstanding section 4 or 6 of the*  
3                             *Federal Trade Commission Act (15 U.S.C. 44,*  
4                             *46), section 2 of McCarran-Ferguson Act (15*  
5                             *U.S.C. 1012), or any other jurisdictional limita-*  
6                             *tion of the Commission, the Commission shall*  
7                             *also enforce this Act, in the same manner pro-*  
8                             *vided in subparagraphs (A) and (B) of this*  
9                             *paragraph, with respect to—*

- 10                             (i) *organizations not organized to*  
11                             *carry on business for their own profit or*  
12                             *that of their members; and*  
13                             (ii) *the business of insurance, and per-*  
14                             *sons engaged in such business.*

15                             (D) *AUTHORITY PRESERVED.—Nothing in*  
16                             *this section shall be construed to limit the au-*  
17                             *thority of the Commission under any other pro-*  
18                             *vision of law.*

19                             (3) *PENALTIES.—*

20                             (A) *ADDITIONAL CIVIL PENALTY.—In addi-*  
21                             *tion to any penalty applicable under the Federal*  
22                             *Trade Commission Act (15 U.S.C. 41 et seq.),*  
23                             *any person that violates this Act shall be liable*  
24                             *for a civil penalty of not more than \$1,000,000.*

1                             (B) *METHOD.*—The penalties provided by  
2                             subparagraph (A) shall be obtained in the same  
3                             manner as civil penalties imposed under section  
4                             18(a)(1)(B) of the Federal Trade Commission  
5                             Act (15 U.S.C. 57a(a)(1)(B)).

6                             (C) *MULTIPLE OFFENSES; MITIGATING FAC-*  
7                             *TORS.*—In assessing a penalty under subpara-  
8                             graph (A)—

9                                 (i) each day of a continuing violation  
10                             shall be considered a separate violation; and  
11                                 (ii) the court shall take into consider-  
12                             ation, among other factors—

13                                 (I) the seriousness of the violation;  
14                                 (II) the efforts of the person com-  
15                             mitting the violation to remedy the  
16                             harm caused by the violation in a  
17                             timely manner; and

18                                 (III) whether the violation was  
19                             intentional.

20                             (b) *ENFORCEMENT BY STATES.*—

21                                 (1) *IN GENERAL.*—If the attorney general of a  
22                             State has reason to believe that an interest of the resi-  
23                             dents of the State has been or is being threatened or  
24                             adversely affected by a practice that violates this Act,  
25                             the attorney general of the State may bring a civil ac-

1       *tion on behalf of the residents of the State in an ap-*  
2       *propriate district court of the United States to obtain*  
3       *appropriate relief.*

4              (2) *RIGHTS OF THE COMMISSION.—*

5              (A) *NOTICE TO THE COMMISSION.—*

6                  (i) *IN GENERAL.—Except as provided*  
7        *in clause (iii), the attorney general of a*  
8        *State, before initiating a civil action under*  
9        *paragraph (1), shall provide written notifi-*  
10       *cation to the Commission that the attorney*  
11       *general intends to bring such civil action.*

12                  (ii) *CONTENTS.—The notification re-*  
13        *quired under clause (i) shall include a copy*  
14        *of the complaint to be filed to initiate the*  
15       *civil action.*

16                  (iii) *EXCEPTION.—If it is not feasible*  
17        *for the attorney general of a State to pro-*  
18        *vide the notification required under clause*  
19        *(i) before initiating a civil action under*  
20        *paragraph (1), the attorney general shall*  
21        *notify the Commission immediately upon*  
22        *instituting the civil action.*

23              (B) *INTERVENTION BY THE COMMISSION.—*

24        *The Commission may—*

1                             (i) intervene in any civil action  
2                             brought by the attorney general of a State  
3                             under paragraph (1); and

4                             (ii) upon intervening—

5                                 (I) be heard on all matters arising  
6                             in the civil action; and

7                                 (II) file petitions for appeal of a  
8                             decision in the civil action.

9                             (3) CONSTRUCTION.—Nothing in this subsection  
10                             may be construed to prevent the attorney general of  
11                             a State from exercising the powers conferred on the  
12                             attorney general by the laws of the State to conduct  
13                             investigations, to administer oaths or affirmations, or  
14                             to compel the attendance of witnesses or the produc-  
15                             tion of documentary or other evidence.

16                             (4) VENUE; SERVICE OF PROCESS.—

17                                 (A) VENUE.—Any action brought under  
18                             paragraph (1) may be brought in—

19                                 (i) the district court of the United  
20                             States that meets applicable requirements  
21                             relating to venue under section 1391 of title  
22                             28, United States Code; or

23                                 (ii) another court of competent juris-  
24                             diction.

1                             (B) *SERVICE OF PROCESS.*—In an action  
2                             brought under paragraph (1), process may be  
3                             served in any district in which—

4                                 (i) the defendant is an inhabitant,  
5                             may be found, or transacts business; or  
6                                 (ii) venue is proper under section 1391  
7                             of title 28, United States Code.

8                             (5) *ACTIONS BY OTHER STATE OFFICIALS.*—

9                             (A) *IN GENERAL.*—If an attorney general  
10                             lacks appropriate jurisdiction to bring a civil  
11                             action under paragraph (1), any other officer of  
12                             a State who is authorized by the State to do so  
13                             may bring a civil action under paragraph (1),  
14                             subject to the same requirements and limitations  
15                             that apply under this subsection to civil actions  
16                             brought by attorneys general.

17                             (B) *CLARIFICATION OF AUTHORITY.*—The  
18                             authority provided by subparagraph (A) shall  
19                             supplant, and not supplement, the authorities of  
20                             State attorneys general under paragraph (1).

21                             (C) *SAVINGS PROVISION.*—Nothing in this  
22                             subsection may be construed to prohibit an au-  
23                             thorized official of a State from initiating or  
24                             continuing any proceeding in a court of the

1           *State for a violation of any civil or criminal law*  
2           *of the State.*

3           (c) *AFFIRMATIVE DEFENSE.*—*In an action brought*  
4 *under this section to enforce section 2, it shall be an affirm-*  
5 *ative defense, on which the defendant has the burden of per-*  
6 *suasion by a preponderance of the evidence, that the conduct*  
7 *alleged to be a violation of section 2 was nonpretextual and*  
8 *reasonably necessary to—*

- 9           (1) *prevent a violation of, or comply with, Fed-*  
10 *eral or State law;*  
11           (2) *protect patient safety; or*  
12           (3) *protect patient access.*

13 **SEC. 7. EFFECT ON STATE LAWS.**

14           *Nothing in this Act shall be construed to preempt, dis-*  
15 *place, or supplant any State laws, rules, regulations, or re-*  
16 *quirements, or the enforcement thereof.*

17 **SEC. 8. DEFINITIONS.**

18           *In this Act:*

19           (1) *COMMISSION.*—*The term “Commission”*  
20 *means the Federal Trade Commission.*

21           (2) *COVERED INDIVIDUAL.*—*The term “covered*  
22 *individual” means a current or former employee, con-*  
23 *tractor, subcontractor, service provider, or agent of a*  
24 *pharmacy benefit manager, health plan, pharma-*

1       *ceutical manufacturer, pharmacy, or any affiliate,*  
2       *subsidiary, or agent thereof.*

3             (3) *HEALTH PLAN.*—The term “*health plan*”  
4       *means any group or individual health insurance plan*  
5       *or coverage, including any health insurance plan or*  
6       *coverage sponsored or funded by the Federal Govern-*  
7       *ment or the government of any State, Territory, or*  
8       *subdivision thereof.*

9             (4) *PHARMACY BENEFIT MANAGER.*—The term  
10      “*pharmacy benefit manager*” means any entity that  
11      provides *pharmacy benefit management services* on  
12      behalf of a *health plan*, a *payer*, or *health insurance*  
13      *issuer.*

14             (5) *PHARMACY BENEFIT MANAGEMENT SERVICES.*—The term “*pharmacy benefit management services*” means, pursuant to a written agreement with a *payer* or *health plan* offering group or individual *health insurance coverage*, directly or through an intermediary, the service of—

20                 (A) negotiating terms and conditions, including rebates and price concessions, with respect to a *prescription drug* on behalf of the *health plan*, *coverage*, or *payer*; or

24                 (B) managing the *prescription drug benefits* provided by the *health plan*, *coverage*, or *payer*,

1       *which may include formulary management the*  
2       *processing and payment of claims for prescrip-*  
3       *tion drugs, the performance of drug utilization*  
4       *review, the processing of drug prior authoriza-*  
5       *tion requests, the adjudication of appeals or*  
6       *grievances related to the prescription drug ben-*  
7       *efit, contracting with network pharmacies, or the*  
8       *provision of related services.*

9             (6) *PREScription DRUG.*—The term “prescrip-

10          *tion drug” means—*

11             (A) *a drug, as that term is defined in sec-*  
12          *tion 201(g) of the Federal Food, Drug, and Cos-*  
13          *metic Act (21 U.S.C. 321(g)), that is—*

14             (i) *approved by the Food and Drug*  
15          *Administration under section 505 of such*  
16          *Act (21 U.S.C. 355); and*

17             (ii) *subject to the requirements of sec-*  
18          *tion 503(b)(1) of such Act (21 U.S.C.*  
19          *353(b)(1));*

20             (B) *a biological product as that term is de-*  
21          *fined in section 351 of the Public Health Service*  
22          *Act (42 U.S.C. 262(i)(1)); or*

23             (C) *a product that is biosimilar to, or inter-*  
24          *changeable with, a biologic product under section*

1           *351 of the Public Health Service Act (42 U.S.C.*  
2           *262(i)).*

**Calendar No. 647**

117TH CONGRESS  
2D SESSION  
**S. 4293**

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**A BILL**

To prevent unfair and deceptive acts or practices and the dissemination of false information related to pharmacy benefit management services for prescription drugs, and for other purposes.

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DECEMBER 14, 2022

Reported with an amendment